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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/551,151	04/14/2000	Thor Borgford	10447-011	1104

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EXAMINER	
LIU, SAMUEL W	

ART UNIT	PAPER NUMBER
1653	5

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/551,151	BORGFORD, THOR	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *none* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-39* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-14 and 39, drawn to an isolated polynucleotide and vectors, classified in class 536, subclasses 23.5, 24.31; and class 435, subclass 320.1, 252.3 and 325+, while a pharmaceutical composition (claim 39) comprising the polynucleotide is classified in class 514, subclass 44.

II. Claims 15-26 and 38, drawn to a recombinant protein, classified in Class 530, subclasses 300 and 350, while the pharmaceutical composition (claim 38) comprising the protein is classified in class 514, subclass 12.

III. Claims 27-29, drawn to a method of inhibiting cells of a tissue affected by a disease comprising preparing and transferring the polynucleotide in to the cells and expressing the polynucleotide thereof, classified in class 536, subclasses 23.5, 24.31; class 435, subclasses 18, 252.3, 320.1, 325+ and 440; class 424, subclasses 93.7 and 94.6; and class 514, subclass 44.

IV. Claim 37, drawn to a method of preparing a pharmaceutical for treating a mammal with a disease state, wherein the pharmaceutical comprises the polynucleotide, classified in class 536, subclasses 23.5, 24.31; class 800, subclass 14; class 435, subclasses 18, 252.3, 320.1, 325+ and 440; class 424, subclasses 93.7 and 94.6; and class 514, subclass 44.

V. Claim 30, 34 and 36, drawn to a method of inhibiting cells of a tissue affected by a disease comprising contacting the cells with the protein produced, classified in and class 514, subclass 2; class 536, class 424, subclasses 93.7 and 94.6; class 435, subclasses 18, 252.3, 320.1, 325+ and 440.

VI. Claims 31, 33 and 35, drawn to a method of treating a disease state comprising administering the polypeptide to an animal and preparing a pharmaceutical composition for the treatment, classified in class 514, subclass 2; class 536, subclasses 23.5, 24.31; class 435, subclasses 18, 70.1, 252.3, 320.1, 325+, 440 and 455; class 424, subclasses 93.7, 94.6 and 278.1.

VII. Claim 32, drawn to a method of treating a disease state comprising administering the polynucleotide to an mammal, classified in class 514, subclass 44; class 536, subclasses 23.5, 24.31; class 800, subclass 14; class 435, subclasses 18, 70.1, 252.3, 320.1, 325+, 440 and 455; class 424, subclasses 93.7, 94.6 and 278.1.

The inventions are distinct, each from the other for the following reasons:

Inventions I and II are patentably distinct from one another because of the materially different structures of the compounds claimed. The Invention I is drawn to polynucleotide while Invention II to polypeptide. The biopolymer that are the subject of each group are independent and/or patentable distinct from each other because each biopolymer is structurally distinct. The biopolymers of each invention would be expected to exhibit different physical and chemical properties, and are capable of separate manufacture or use.

Inventions III, IV, V, VI and VII are directed to different and/or distinct methods. Although there are no provisions under the section for "Relationship of Invention" in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper between the methods of Inventions III and IV since they constitute patentably distinct inventions comprising methodologies, starting material, objectives, technical considerations, ingredients, endpoint or/and treatment outcome. Therefore, each method is patentably distinct.

Invention I related to Inventions III, VII and IV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of Invention I can be immobilized on the surface of a DNA-microarray chip for genomic typing.

Invention I is unrelated to Inventions V and VI. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mechanism of using protein to treat a disease or inhibiting cellular regulation is distinct from that of using the polypeptide thereof, *e.g.*, the polynucleotide can be used in different process such as hybridization whereas the polypeptide is not capable of do so.

Invention II is related to Inventions V and VI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide produced by Invention II can be used in proteinchip array to investigating signal transduction pathway, for example, which is a material different process from the processes of Invention V and VI using the protein.

Invention II is unrelated to Inventions III, IV and VII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the mechanism of using polynucleotide to inhibit cellular regulation is distinct from using the polypeptide, *e.g.*, the polypeptide can be used for raising an antibody that recognizes and binds the polypeptide.

Because these inventions are distinct for the reasons given above and since they have acquired a separate status in the art as shown by their different classification and/or divergent subject matter, and/or are separately and independently searched, restriction for examination purposes as indicated is proper.

Additional election

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed 37 C.F.R. 1.143). In the response, applicant is to indicate (1) the elected group and indicate (2) the further election as required below. Please note that this is not species election.

Where Group I is elected, under 35 U.S.C. 121, applicant is also required to elect (A) one toxin polypeptide form claims 4-5 and 6-7; (B) one type of protease from claims 8 and 10; and (C) one nucleotide sequence from claim 12, and one liker nucleotide sequence from claim 3, since each of the polypeptides and the polynucleotides are structurally distinct/different from one another. Applicant should identify the elections.

Where Group II is elected, applicant is required under 35 U.S.C. 121 to elect one linker polynucleotide sequence from claim 3 from which claim 39 depends, because each of the linker sequence encode by the polynucleotide has different specificity recognized by the different protease.

Where Group II is elected, applicant is also required under 35 U.S.C. 121 to elect: (A) one A chain from claims 18 and 19 and one B chain form claims 20 and 21, because each polypeptide chain is chemically different; (B) one protease from claim 22 since each protease has different/distinct enzymatic specificity; (C) one type of virus from claim 24; and (D) one liker nucleotide sequence and one insert nucleotide sequence from claim 26.

Where Group III is elected, applicant is required under 35 U.S.C. 121 to elect one disease state from claim 29, because each states are pathologically distinct from one other, *e.g.*, pathological state of cancer is distinct from fungal infection.

Where Group IV and V are elected, applicant is required under 35 U.S.C. 121 to elect one disease state from claim 37 and claim 36, respectively, because each states are pathologically distinct from one other, *e.g.*, pathological state of cancer is distinct from fungal infection.

Where Group VI is elected, applicant is also required under 35 U.S.C. 121 to elect one linker peptide sequence from claim 33, because each sequence is characterized by the different specificity toward different protease, *i.e.*, recognized by the different protease.

Where Group VII is elected, applicant is also required under 35 U.S.C. 121 to elect one polynucleotide sequence form claim 12 from which claim 32 depends, because each of the polynucleotide sequences is structurally different and the sequence-encoded linker peptides are recognized by the different proteases.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu, Ph.D. whose telephone number is 703-306-3483. The examiner can normally be reached Monday-Friday 9:00 -5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communication and (703) 305-3014 for the after final communication.

Papers related to this application may be submitted by facsimile transmission to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1) and must conform to the notice published in the Official Gazette, 1096 OG 30 (15 November 1989). The telephone number assigned to Art Unit 1804 in the CM1 PTO Fax Center is (703) 308--4242 or 305-3014.

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January 18, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER